International Pharmaceutical Excipients Council
Of The Americas

R. Christian Moreton, Ph.D
Chairman

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Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0276 Proposed Regulations for Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act Of 2002

Dear Sirs:

The following comments are submitted on behalf of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas). IPEC-Americas is an industry trade association formed in 1991 whose members are companies which either manufacture excipients or are firms which use them in dietary supplements and finished pharmaceutical dosage forms. As the agency is aware, many excipients used in these products are food additives or food ingredients and some, such as gelatin and starches, frequently may be present in food or drugs in the same physical grade. Some materials also have uses outside the food and pharmaceutical industries, e.g. as adhesives (starches and gums), as fillers (silica and other inorganic materials), etc. that would not require either registration or prior notification of intent to import.

In addition, a number of member companies of both types regularly import materials affected by the regulations either from outside manufacturing or brokerage sources, or from their own foreign affiliates. Since pharmaceutical use typically is only a small percentage of an average excipient's total usage, overseas suppliers, even those which are subsidiaries of member companies, seldom know how their products will be used or in what kind of product. As a result, IPEC-Americas members are greatly affected by the proposed regulations and we appreciate the opportunity to provide comments.

We hope our comments and suggestions will be helpful, as we fully support the Agency's intent and the goal of the proposed regulations to protect the U.S. food supply. Given the global nature of the food and food ingredient industries, this is no easy task.

It is this, and the fact that few companies that supply excipients can be certain about the ultimate use of their material at the time of importation, that gives us and our members great concern. For example, it would seem prudent for IPEC-Americas members to assure themselves that foreign producers of materials intended for use in the U.S. are properly registered under the Act as producers of both food and pharmaceutical ingredients. To do

02N-0276 C145

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otherwise would seem to expose the producer and an importing company to possible future liability or at least denied entry of the material.

We also note there is a declared intent to eventually have a similar sytem for registration of pharmaceutical excipient manufacturing sites. IPEC-Americas suggests that much time and effort could be saved, by both industry and the government agencies, by having one joint set of forms covering both registration systems; in effect having one form allowing registration of sites of manufacture for both food ingredients and pharmaceutical excipients that could be used to notify the Agency of the site of manufacture of a particular material or materials, and that would not need a separate registration for each material manufactured at that site.

Thank you for the opportunity to comment on the proposed regulations.

Yours sincerely,

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